

February 24, 2021

By Electronic Mail

United States Environmental Protection Agency
Dion Novak, Remedial Project Manager (SR-6J)
77 West Jackson Boulevard
Chicago, Illinois 60604
(312) 886-4737
novak.dion@epa.gov

**Re: Boston Scientific Corporation's Response to EPA's Special Notice Letter dated
November 24, 2020 regarding the Franklin Street Groundwater Site**

Dear Mr. Novak:

On behalf of Boston Scientific Corporation ("BSC"), I am writing in response to the United States Environmental Protection Agency's ("EPA") November 24, 2020 Special Notice Letter regarding the Franklin Street Groundwater Site ("the Site"), located in Spencer, Indiana. Pursuant to EPA's authority under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended ("CERCLA"), 42 U.S.C. §§ 9601-9675, BSC understands that EPA is planning to conduct certain response activities at the Site. For the reasons set forth below, based on the information available at this time, BSC is declining to participate in formal negotiations with EPA to reach a settlement to conduct or finance a remedial investigation and feasibility study at the Site. BSC is interested in cooperating with EPA and will reconsider its participation should new information become available regarding any potential contribution by BSC to the Site.

I. BACKGROUND

Boston Scientific is a medical device manufacturer that leases and operates a facility located at 780 Brookside Drive in Spencer, Indiana ("the BSC Facility"). The 780 Brookside Drive property is currently owned by TBH, LLC ("TBH"). BSC has leased this property since 1986, when it acquired Van-Tec, Inc. ("Van-Tec"). BSC's operations at the BSC Facility generally consist of manufacturing and developing products to treat kidney stones and digestive tract diseases primarily in the Urology, Pelvic Health, Endoscopy areas along with components for BSC devices used across many medical specialties. The manufacture of medical devices is an inherently clean operation because these devices are typically used within the human body. BSC is required to maintain a controlled sanitary environment that is highly regulated by the United States Food and Drug Administration.

BBP Water Corporation ("BBP") is a private water corporation that provides drinking water to the town of Spencer. BBP operates three active municipal wells and at least two wells that are non-active but still operational. Tetrachloroethylene ("PCE") was first detected in treated drinking water at a concentration of 1.2 µg/L in June 2011 and at 1.4 µg/L in February 2012. Additional testing by the Indiana Department of Environmental Management ("IDEM") in 2014 resulted in the detection of

PCE in all three active BBP wells, with one well exceeding 5.0 µg/L (the EPA maximum contaminant level).

In 2015, IDEM carried out a site investigation at the Site, wherein it collected and analyzed 19 groundwater and nine soil samples for VOCs. IDEM published the results of its site investigation in a final report dated March 15, 2016 (hereafter, the "2016 IDEM Site Investigation Report"). As set forth in the 2016 IDEM Site Investigation Report, IDEM determined the groundwater flow to be primarily towards the southwest (away from the BSC Facility) and noted that the river significantly influences groundwater flow in the area.

PCE was detected in one soil sample at a concentration of 1,200 µg/kg and some of the groundwater samples. Notably, the highest PCE concentration of 220 µg/L was detected in the groundwater sample (E2TJ8) taken at the location of the former Ranard's Cleaners (which operated from approximately 1959-2002 under various names). PCE also was detected at a level of 180 µg/L in the groundwater sample (E2TJ2) taken at the former Richardson Cleaners site (which operated from approximately 1948-1974 under various names) and at 140 µg/L at a private residential well (E2TG8), downgradient of the former Ranard's Cleaners site.

The groundwater sampling results and soil sampling results from the locations closest to the BSC Facility all indicate a non-detect for PCE. See Attachment A. Specifically, the Affidavit of Nick Cooper ("Cooper Affidavit"), an IDEM Senior Environmental Manager with who conducted the sampling during IDEM's investigation, indicates that monitoring well E2W52 (located directly downgradient of the BSC Facility) was non-detect for chlorinated VOCs, including PCE, which had been found in the groundwater at the Franklin Street Site.¹ See Cooper Affidavit at 5 and 10. Samples from next closest monitoring well to the BSC Facility, E2W56, were collected as background samples during IDEM's 2015 investigation and similarly indicated non-detect for chlorinated VOCs. *Id.*

Consistent with the above findings, IDEM does not identify the source of contamination in its report but states that, "PCE is a common contaminant found at dry cleaning facilities." 2016 IDEM Site Investigation Report at 3. The Cooper Affidavit states that "several facilities that utilize PCE, including three (3) historic dry-cleaners were identified in the town of Spencer" and also notes that "the most recent dry-cleaner operated from the early 1980s until 2002 [i.e., Ranard's Cleaners] and was located less than 0.5 miles northeast of the [BBP] wellfield." Cooper Affidavit at 2; see also 2016 IDEM Site Investigation Report at 3. BSC is mentioned in the report, but no connection to the Site is identified.

BBP installed a treatment system consisting of air strippers in 2016-2017, which has eliminated all traces of VOCs in finished water. In 2018, EPA added the Site to the National Priorities List (NPL) based solely on "groundwater migration pathway" as the basis for listing the Site. See EPA Hazard Ranking System Documentation Record at 1 (Revised May 2018).

In 2019, EPA issued an information request to BSC pursuant to its authority in Section 104(e) of CERCLA. On June 3, 2019, BSC responded to this request (hereafter BSC's "Section

¹ In his affidavit, Cooper indicates that groundwater sample E2W53 "was analyzed outside of holding times" and therefore potential detections of VOCs from an upgradient source could not be confirmed. However, this is the only groundwater sampling data from a location near the BSC Facility.

104(e) Response”), providing EPA with requested information including, among other things: manifests of hazardous waste; annual reports showing waste codes for hazardous materials used at or transported from the BSC facility; chemical purchase records, and materials safety data sheets.

None of the BSC records indicate the use of PCE or trichloroethylene (“TCE”) at the BSC Facility. BSC’s response did identify the use of certain unrelated substances, namely benzene, xylene, acetone, ethylbenzene, and toluene, as set forth in the table in Attachment B. However, these substances are components of common cleaning agents which are routinely used in manufacturing operations, as well as components of gasoline and motor fuels. The substances noted are pervasive in a variety of industries and likely used by several businesses, as well as private homes, throughout the Town of Spencer. More importantly, there is no record of a release of any of these substances at the BSC facility. The mere use of a substance alone does not cause BSC to be a potentially responsible party.

On March 6, 2020, EPA issued a general notice of potential liability to BSC indicating that EPA “ha[d] received information that [BSC] may have owned or operated the Site or generated or transported hazardous substances that were disposed of at the Site.” See General Notice of Potential Liability Letter from EPA to BSC at 1 (Mar. 6, 2020). In its letter, EPA identified no facts supporting this allegation.

On November 24, 2020, EPA issued its Special Notice Letter to BSC identifying BSC as one of 15 potentially responsible parties (“PRPs”) “that contributed hazardous substances to the Site,” and stating that “[u]nder the federal Superfund law, [BSC] and the other PRPs at the Site are responsible for the costs of cleanup.” Once again, EPA identified no facts supporting this allegation. On January 8, 2021, BSC (joined by TBH) met with EPA to review the facts related to the Site and to request clarification of EPA’s basis for BSC’s liability. EPA provided no new evidence or facts during that meeting.

II. BSC IS NOT LIABLE UNDER CERCLA

Under CERCLA, a party can only be liable for a release of hazardous substances if it fits into one of four statutorily defined classes of responsible parties:

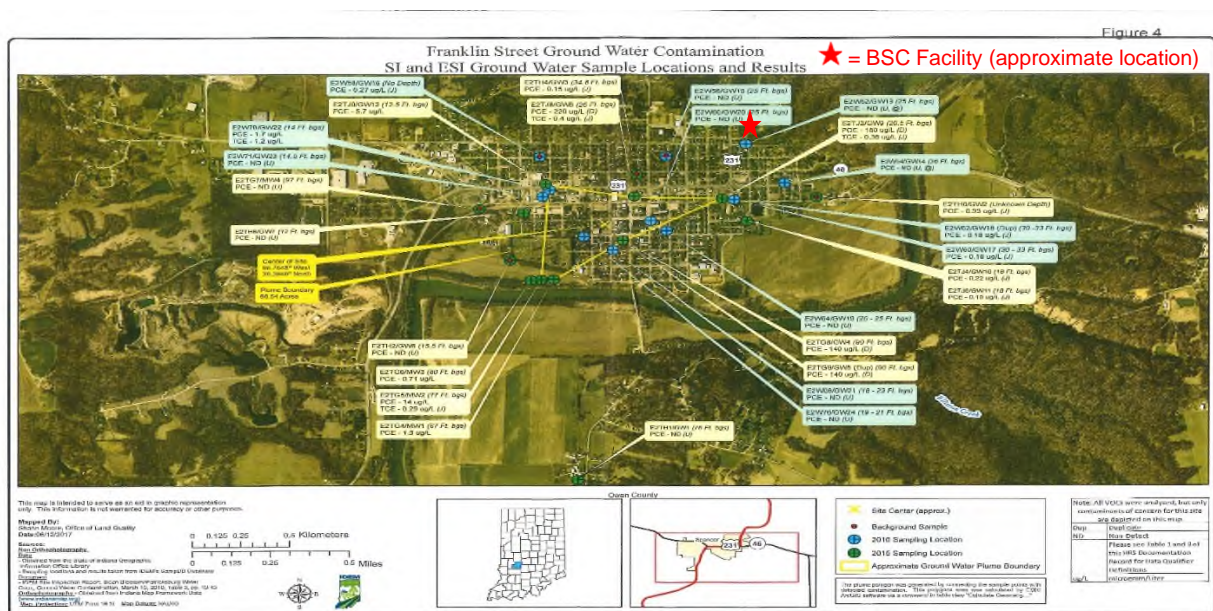
- (1) The owner and operator of a vessel or a facility,
- (2) Any person who at the time of disposal of any hazardous substance owned or operated any facility at which such hazardous substances were disposed of,
- (3) Any person who by contract, agreement, or otherwise, arranged for disposal or treatment, or arranged with a transporter for transport for disposal or treatment, of hazardous substances owned or possessed by such person, by any other party or entity, at any facility or incineration vessel owned or operated by another party or entity and containing such hazardous substances, or
- (4) any person who accepts or accepted any hazardous substances for transport to disposal or treatment facilities, incineration vessels or sites selected by such person, from which there is a release, or a threatened release which causes the incurrence of response costs, of a hazardous substance

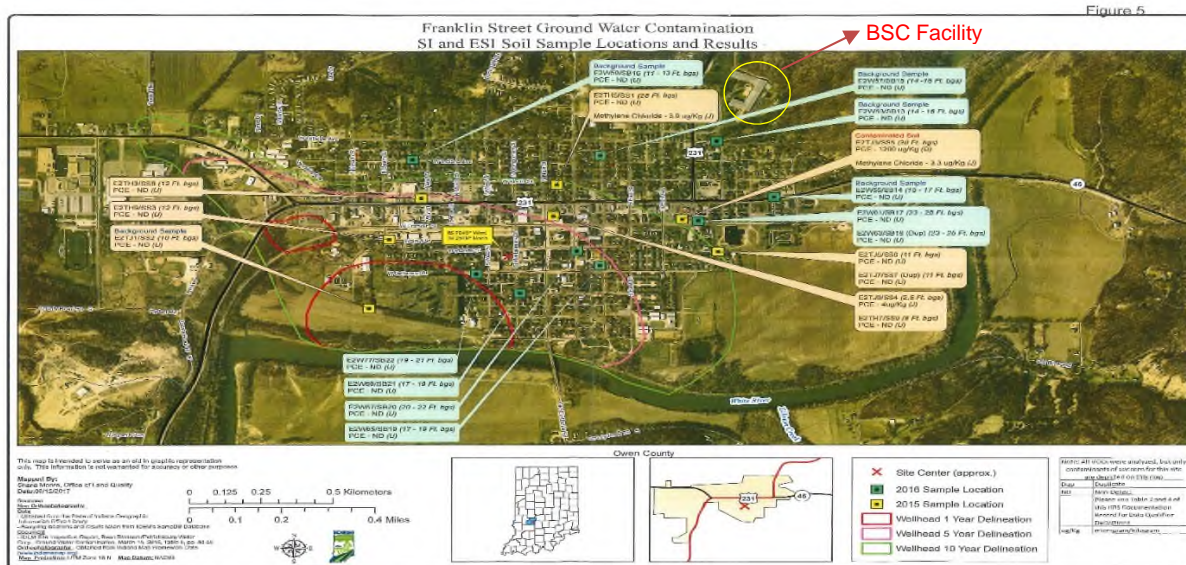
42 U.S.C. § 9607(a). In addition, CERCLA defines “facility” to include “any site or area where a hazardous substance has been deposited, stored, disposed of, or placed, or otherwise *come to be located*.” 42 U.S.C. § 9601(9)(B) (emphasis added).

Based on the information available at this time, BSC is not liable under CERCLA because it has no temporal or geographic nexus to the Site that causes it to be one of the four classes of persons liable for releases of hazardous substances under CERCLA.

A. BSC is not a Current or Former Owner or Operator

To qualify as a PRP as an owner or operator, a party must either be a current "owner" or "operator" of a facility or have owned or operated the facility at the time hazardous substances were disposed of there. 42 U.S.C. § 9607(a)(1), (2). BSC is not a current or former owner or operator of the land upon which hazardous substances have come to be located. The BSC Facility is located at 780 Brookside Drive, which is neither adjacent nor proximate to the Franklin Street Groundwater plume. The maps below show the location of the BSC facility northeast of, and some distance from, the delineated groundwater plume. Importantly, groundwater flow is towards the southwest.





As shown above, both the groundwater sampling and the soil sampling most proximate to the BSC Facility between the delineated plume and the BSC facility are non-detect for PCE, the principal contaminant of concern. Accordingly, BSC is not liable as a former or current owner or operator because it does not own the site where the hazardous substances have come to be located.

B. BSC is not an Arranger

As stated above, § 9607(a)(3) applies to an entity that “arrange[s] for disposal ... of hazardous substances.” Based on a searching review of BSC records, there is no evidence that BSC arranged for the disposal of hazardous substances at the Site. The location of the plume in the proximate center of Spencer, the nature of the hazardous substances determined to be of concern at the Site (e.g., PCE), the nature of the business activity that occurred within the area of the plume (including several historical dry-cleaning operations), and IDEM’s findings each indicate that the source of the contamination is not a remotely located business like BSC.

C. BSC is not a Transporter

To qualify as a “transporter” under § 107(a)(4), a party must have “accepted hazardous substances for transport and either selected the disposal facility or had substantial input into deciding where the hazardous substance should be disposed.” *United States v. USX Corp.*, 68 F.3d 811, 820 (3d Cir. 1995), *as amended* (Dec. 14, 1995). BSC is not and has never been a transporter of hazardous substances to the Site, nor is BSC aware of any evidence to support a contrary conclusion.

III. CONCLUSION

At this time, EPA has not provided BSC with documentation, information, or sampling data indicating that BSC contributed to the groundwater contamination at the Site. Accordingly, based on the available information, BSC cannot be properly included within one of the four classes of CERCLA liable parties. Accordingly, BSC is declining EPA’s invitation as set forth in its Special Notice Letter.

BSC remains committed to cooperating with EPA and will reevaluate its participation should new information become available, including any new sampling data, that suggests BSC is a source of the contamination at the Site.

Sincerely,

A handwritten signature in blue ink, appearing to read "Adam M. Kushner".

Adam M. Kushner
Partner

adam.kushner@hoganlovells.com

Direct Dial: 202-637-5724

(Enclosures)

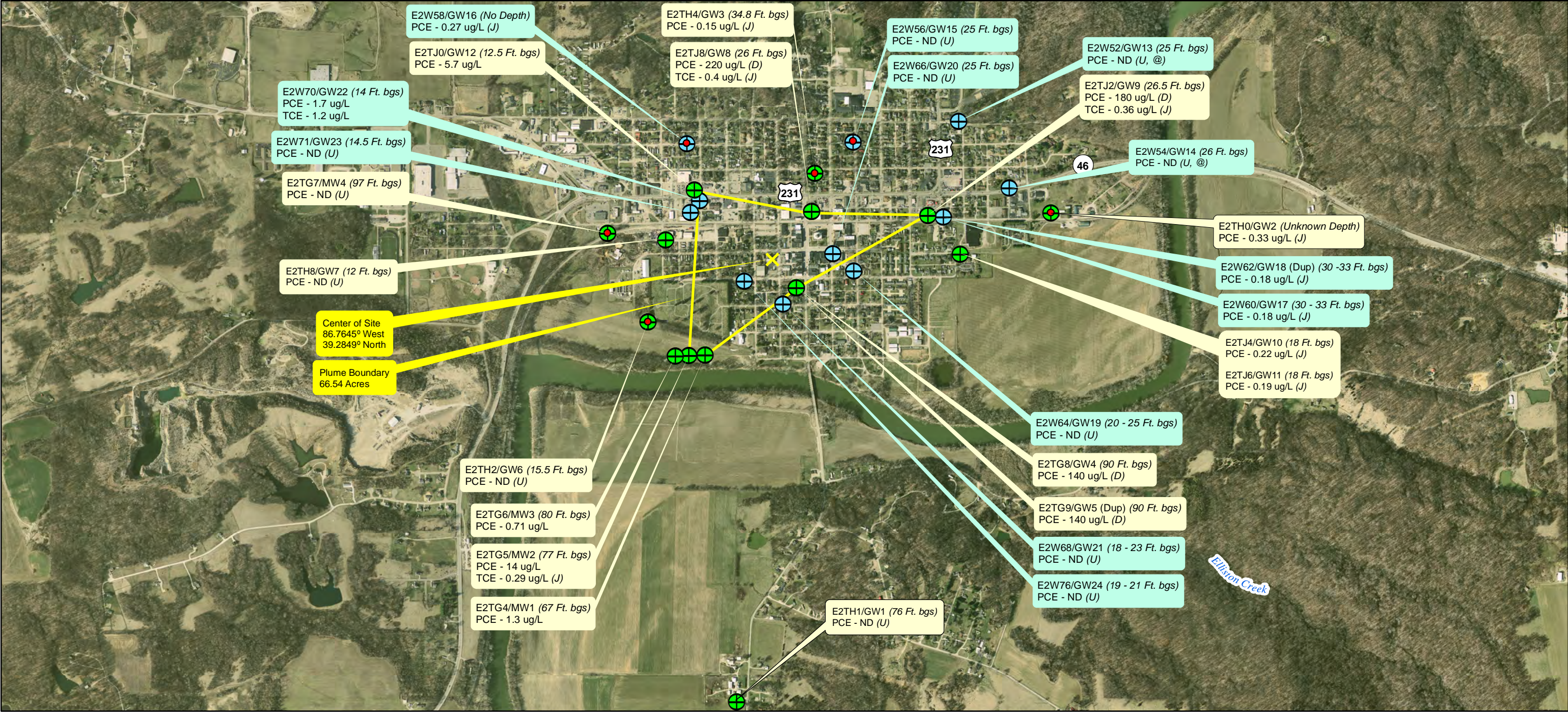
cc: Eileen Hunter, BSC
Nicole Wood-Chi, EPA

Attachment A

BSC Response to EPA's November 24, 2020
Special Notice Letter

Franklin Street Groundwater Contamination SI and ESI Groundwater Sample Locations and Results

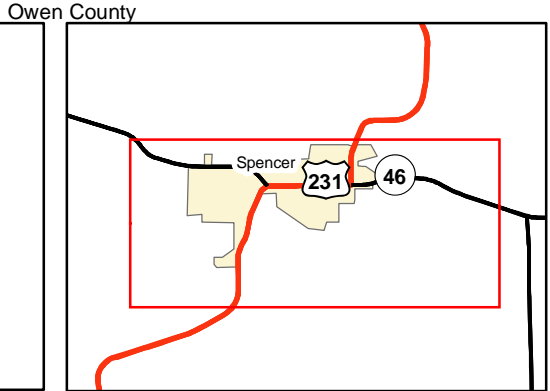
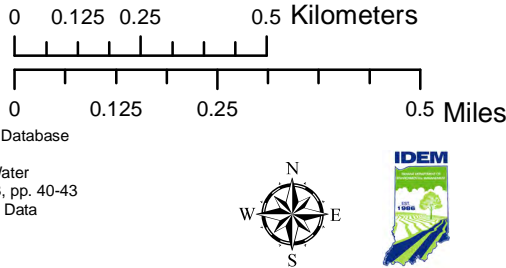
Figure 4



This map is intended to serve as an aid in graphic representation only. This information is not warranted for accuracy or other purposes.

Mapped By:
Shane Moore, Office of Land Quality
Date: 06/12/2017

Sources:
Non Orthophotography
Data
- Obtained from the State of Indiana Geographic Information Office Library
- Sampling locations and results taken from IDEM's SampDB Database Document
- IDEM Site Inspection Report, Bean Blossom/Patricksborg Water Corp., Ground Water Contamination, March 15, 2016, Table 3, pp. 40-43
Orthophotography - Obtained from Indiana Map Framework Data (www.indianamap.org)
Map Projection: UTM Zone 16 N **Map Datum:** NAD83



Legend:

- X Site Center (approx.)
- Background Sample
- ⊕ 2016 Sampling Location
- ⊕ 2015 Sampling Location
- Approximate Ground Water Plume Boundary

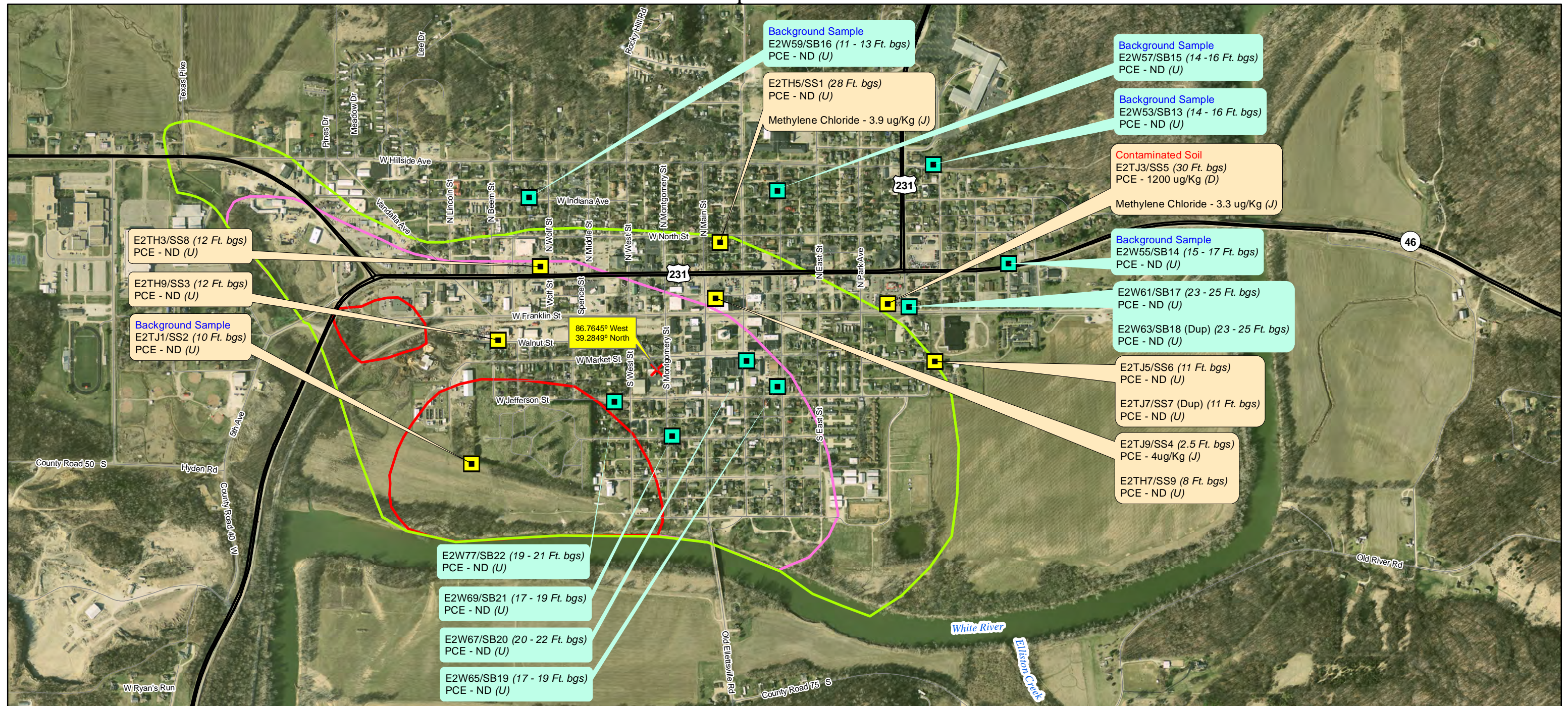
The plume polygon was generated by connecting the sample points with detected contamination. This polygons area was calculated by ESRI ArcGIS software via a command in table view "Calculate Geometry...."

Note: All VOCs were analyzed, but only contaminants of concern for this site are depicted on this map

Dup	Duplicate
ND	Non-Detect
	Please see Table 1 and 3 of this HRS Documentation Record for Data Qualifier Definitions
ug/L	microgram/Liter

Franklin Street Groundwater Contamination SI and ESI Soil Sample Locations and Results

Figure 5



This map is intended to serve as an aid in graphic representation only. This information is not warranted for accuracy or other purposes.

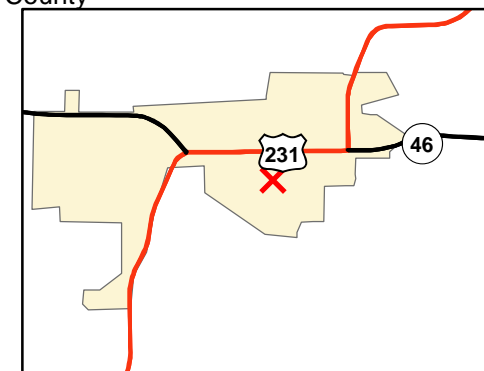
Mapped By:
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Sources:
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- Obtained from the State of Indiana Geographic Information Office Library
- Sampling locations and results taken from IDEM's SampDB Database Document
- IDEM Site Inspection Report, Bean Blossom/Patricksburg Water Corp., Ground Water Contamination, March 15, 2016, Table 5, pp. 44-45
Orthophotography - Obtained from Indiana Map Framework Data (www.indianamap.org)
Map Projection: UTM Zone 16 N **Map Datum:** NAD83

0 0.125 0.25 0.5 Kilometers
0 0.1 0.2 0.4 Miles



Owen County



- ✗ Site Center (approx.)
- 2016 Sample Location
- 2015 Sample Location
- Wellhead 1 Year Delineation
- Wellhead 5 Year Delineation
- Wellhead 10 Year Delineation

Note: All VOCs were analyzed, but only contaminants of concern for this site are depicted on this map

Dup	Duplicate
ND	Non-Detect
	Please see Table 2 and 4 of this HRS Documentation Record for Data Qualifier Definitions
ug/Kg	microgram/kilogram

Attachment B

BSC Response to EPA's November 24, 2020
Special Notice Letter

Table 1

Substances in the Franklin Street Groundwater Plume	Substances Identified by BSC in its Response to EPA's CERCLA information request
Tetrachloroethylene (PCE)	D001 – ignitable
Trichloroethylene (TCE)	D018 – benzene
Acetone	D035 – methyl ethyl ketone (MEK)
MBTE	F003 – xylene, acetone, ethylbenzene
Cyclohexane	F005 – toluene, MEK
Benzene	1,1,1 trichloroethane (purchased chemicals summary)
Methylcyclohexane	Toluene spill 1990s (employee interviews)
Toluene	
M-, p-xylene	
Carbon disulfide	
Ethylbenzene	
O-xylene	
bromodichloromethane	